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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/000,005	11/20/2001	Eleanor L. Schuler	0607-1006	7962

7590 02/23/2007

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EXAMINER	
ALTER, ALYSSA M	
ART UNIT	PAPER NUMBER
3762	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/000,005	SCHULER ET AL.	
	Examiner	Art Unit	
	Alyssa M. Alter	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6,11,15 and 23-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6,11,15 and 23-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Terminal Disclaimer

The terminal disclaimers filed on May 22, 2006 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of US 6,937,903 B2 (Application No. 10/847,738), US Patent 6,775,573, copending Application Nos. 11/125480 (U.S. Patent Publication 20050251061 A1) and 11/147497 (U.S. Patent Publication 20050261601 A1) have been reviewed and is accepted. The terminal disclaimers have been recorded.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1, 6, 10-11 and 15 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,633,779. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims meet the limitations of the transmitting or broadcasting waveforms to an organ to affect the functioning of an organ in the body.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1 and 23-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The recitation of the limitations of collecting a plurality of waveforms "from an autonomic nervous network in a body" (claim 1), wherein the autonomic nervous network comprises the "vagus nerve" and/or "hypoglossal nerve bundle"(claims 23-24) and the waveforms are "naturally generated" "(claims 1 and 25), in combination with the other elements or steps were not previously described in the specification to reasonable convey necessity for there inclusion into the claimed subject matter.

Response to Arguments

Applicant's arguments filed September 21, 2006 have been fully considered but they are not persuasive.

The Applicant argues that Kennedy "does not teach or even suggest the step of storing a plurality of collected waveforms according to the functions regulated by the collected waveforms or a source of collected waveforms". However, the Applicant also argues that Kennedy fails to teach "a sensor", however, since Kennedy senses signals, there is necessarily a sensor.

Furthermore, the Applicant argues that the waveforms of Kieval et al. are not "naturally generated". However, this limitation only exists in claims 1 and 25. Therefore, claims 6, 11 and 15 do not possess the "naturally generated" limitation and therefore stand rejected under the previous grounds of rejection made of record 8/28/06.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 6, 11 and 15 stand and claims 23-27 is rejected under 35 U.S.C. 102(b) as being anticipated by Kennedy (US 4,852,573) for reasons previously made of record and stated above.

Kennedy teaches a system and method for stimulating and regulating body organ function. The method includes collecting waveforms from the brain or nervous system that are representative of waveforms naturally occurring within a body from a body; at least temporarily storing the collected waveforms in a storage medium (33); and transmitting a first waveform signal including at least a second waveform that *substantially corresponds to* one or more collected waveforms to the nervous system to stimulate organ function. The system includes a source of collected waveforms (33); means for transmitting (22, 31) at least one of the collected waveforms to a body organ; and means for applying (30, 58) the transmitted waveforms to the body organ. Recording electrodes (30, 58) are placed on the body to collect the waveforms in analog form and transmit the waveforms to the storage medium.

Kennedy also discloses on col. 6, lines 58-98, "The signals produced by the nerve fibers in proximity to or touching nerve segment 38 or the bare end 26 of wire 14 will be electrically conducted through the wire to pin 30, which communicates with a recording device 33 outside of the body. In one embodiment of the present invention signals are received from the body in order to analyze neural functions of the body. In an alternative embodiment, electrical signals are transmitted from an extracorporeal transmitter to the nerve fibers in proximity to the electrode. The effects of this stimulation can be observed as motor or other activity". Therefore these waveforms are stored and can affect body function.

As to claims 23-24 and 26-27, the aforementioned claims recite the limitations "wherein the said autonomic nervous network comprises the vagus nerve"(claims 23

and 26) and "wherein the said autonomic nervous network comprises the hypoglossal nerve bundle"(claims 24 and 27). Since the nervous system is interconnected and the autonomic nervous system includes the vagus nerve and the hypoglossal nerve bundle, any waveforms transmitted to the autonomic nervous system, would be transmitted to the autonomic nervous system comprising the vagus nerve and/or the hypoglossal nerve bundle.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 6, 11 and 15 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kieval et al. (US 6,522,926). Kieval et al. discloses a device to "be used to increase or decrease blood pressure, sympathetic nervous system activity and neurohormonal activity, as needed to minimize deleterious effects on the heart, vasculature and other organs and tissues"(col. 21, lines

11-14) by activating the baroreceptors. Kieval et al. also discloses in column 21, lines 15-16 that "the baroreceptor activation devices described previously may also be used to provide antiarrhythmic effects". As seen in figure 3, "the control system 60 generates a control signal as a function of the received sensor signal. The control signal activates, deactivates or otherwise modulates the baroreceptor activation device 70. Typically, activation of the device 70 results in activation of the baroreceptors 30"(col. 9, lines 33-37). The examiner considers the control system to be the storage area where the signals are generated.

In the alternative, Kieval et al. discloses the claimed invention except for the memory to store waveforms. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the control system and method as taught by Kieval et al. with a memory to store waveforms since it was known in the art that storing and recording data can provide physicians with information on the status of their patient.

As to claims 6 and 15, the Applicant merely states a source of collected waveform signals indicative of a body organ functioning. Since Kieval et al. generates a control signal as a function of the received sensor signal, then the signals are indicative of body organ functioning. Furthermore, Kieval et al. does "directly" transmit waveform signals as disclosed in col. 7, lines 33-37.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571) 272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alyssa M Alter
Examiner
Art Unit 3762

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